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EXAMINER MEHTA, ASHWIN D				
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1638				

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/751,363

Applicant(s)

CUNNYNGHAM, CHARLES
THOMAS

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1052004
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Request under Rule 1.105

DETAILED ACTION

Priority

1. In the priority statement in lines 9-11 of page 1 of the specification, the status of U.S. application 09/490,669 should be updated to recite the patent number that issued from it.

Information Disclosure Statement

2. The IDS filed January 5, 2004 contains a PTO-891 that was mailed by the USPTO during prosecution of parent application 09/490,669. The information listed in that form has been considered in the instant application. However, this is not a proper form 1449. Applicants should submit a form 1449 listing the references cited on the 891 form.

Claim Objections

3. Applicant is advised that should claims 2 and 3 be found allowable, claims 5 and 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 2 and 3 depend from different claims than claims 5 and 6. However, the scopes of claims 2 and 5, and of claims 3 and 6, are the same.

Double Patenting

Art Unit: 1638

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-6, 11-18, 23, 24, 28, and 29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,723,900 ('900). Although the conflicting claims are not identical, they are not patentably distinct from each other because: Instant claim 1 is drawn towards any seed comprising at least one set of chromosomes of maize inbred line PHJ8R. This claim encompasses seed of PHJ8R itself, as well as F1 hybrid progeny that have PHJ8R as one parent. Patented claim 1 anticipates instant claim 1, since it is directed to the inbred seed of line PHJ8R. Instant claims 2 and 3 are drawn to a maize plant, or a part thereof, produced by growing the F1 hybrid maize seed of claim 1. Instant claims 5 and 6 are drawn to a maize plant, or a part thereof, produced by growing an F1 hybrid seed that is produced by crossing PHJ8R with a different maize plant. Patented claim 8 is drawn towards a method of producing an F1 hybrid maize seed, comprising crossing a plant

Art Unit: 1638

of line PHJ8R with a different maize plant and harvesting the resultant seed. It would have been obvious to one of ordinary skill in the art to grow seed produced by the method of patented claim 8 to yield the F1 hybrid plant. One would have been motivated to do so to use the F1 hybrid plant in further crosses, for example. Further, the method of patented claims 25 and 30 comprise producing and further crossing F1 hybrid plants that have PHJ8R as one parent. Instant claim 4 is drawn to an F1 hybrid seed produced by crossing PHJ8R with a different maize plant and harvesting the resultant seed. This is the same seed that is produced by the method of patented claim 8. One would have been motivated to carry out the method of patented claim 8, to produce and use the resultant seed. Instant claim 11 is drawn to a maize plant having all the characteristics of PHJ8R. Patented claim 24 is drawn to a maize plant, or part thereof, that has all the characteristics of PHJ8R, and therefore anticipates instant claim 11. Patented claim 1 also anticipates instant claim 11, as instant claim 11 encompasses the seed of inbred line PHJ8R itself. Instant claim 12 is drawn to a method of crossing the plant of claim 11 with itself or another maize plant to form seed. This process is anticipated by the method of patented claim 8. Instant claims 13-14 are drawn towards seeds that are formed by carrying out the process of patented claim 8, and growing the resultant seed. One would have been motivated to grow the resultant seed and produced the hybrid plant, to use it in further crosses or to produce edible corn. Instant claim 17 is drawn to a cell of the plant of claim 11, which is anticipated by patented claims 2 and 24. Instant 18 is drawn to a seed comprising the cell of claim 18, which is anticipated by patented claim 1. Instant claim 23 limits the plant of claim 11 by further requiring it to comprise a gene conferring male sterility. Instant claim 24 further limits the plant of claim 11 by further requiring it to comprise a transgene that confers male sterility, herbicide resistance,

Art Unit: 1638

insect resistance, or disease resistance. This is anticipated by patented claims 10, 12, 13, 15, 16, and 18, which are plants produced by transforming PHJ8R with transgenes that confer these traits. Instant claim 28 is drawn towards a method for developing a maize plant in a breeding program using the plant, or parts thereof, of claim 11. Instant claim 29 limits the method of claim 28 by reciting several breeding techniques, including backcrossing and transformation. Patented claims 9, 11, 14, 17, 19, 21, 25, and 30 each anticipate instant claims 28 and 29, as they encompass a method transforming PHJ8R or a method that involves backcrosses. Instant claims 28 and 29 do not indicate when the methods are finished, that is, when the plant is developed.

5. Claims 19-22 and 25-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,723,900 ('900) in view of Larkins (U.S. Patent No. 6,232,535).

Instant claim 19 is drawn to a maize plant having all the physiological and morphological characteristics of inbred line PHJ8R, further defined as having a genome comprising a single locus conversion. Claim 2 of '900 is drawn towards the maize plant of inbred line PHJ8R, and patented claim 24 is drawn towards maize plant having all the physiological and morphological characteristics of inbred line PHJ8R. The patented claims of '900 do not encompass the plant of claim 2 or 24 further comprising a single locus conversion in its genome. However, Larkins defines "single locus conversion" as plants developed through backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to a desirable characteristic conferred by a single locus transferred into the inbred via backcrossing. Larkins discloses that the single locus may be transgenic, which indicates that it

Art Unit: 1638

was initially introduced into the donor line by stable transformation. Larkins discloses that the locus may be a dominant or recessive allele of a gene, and asserts that the locus can confer a trait such as insect resistance, bacterial, fungal or viral disease, and male sterility (col. 10, line 63 to col. 11, line 4). Larkins further discusses this at col. 13, line 59 to col. 17, line 5. It would have been obvious to introduce a single locus conversion into the plant of claim 2 or 24 of '900, following the method of Larkins. One would have been motivated to do so to introduce a further desirable trait, such as herbicide tolerance or resistance to bacterial, fungal, or viral disease, for example, as taught by Larkin.

Instant claim 25 is drawn to a method of producing a maize plant derived from PHJ8R, the method comprising steps of crossing the plant of claim 11 with a second maize plant to obtain progeny, followed by several growing and crossing steps to obtain a derived maize plant. Instant claim 26 limits the derived maize plant to be an inbred. Instant claim 27 further limits claim 26 by crossing the derived inbred with a distinct inbred to produce an F1 hybrid plant. Larkins teaches that breeding methods are used to make plants having desirable traits, and assert that pedigree breeding is used to develop inbreds. Genetic backgrounds from two or more inbred plants are combined into breeding pools from which other inbreds are developed. After selfing for at least 5 generations, an inbred is developed (col. 1, line 15 to col. 2, line 60). Claim 8 of '900 is drawn to a method of crossing PHJ8R with a different maize plant to produce F1 hybrid seed. It would have been obvious to modify this method by crossing the F1 hybrid plant with another plant with a desirable characteristic, in order to produce a progeny plant of a subsequent generation. Alternatively, the plant could have been further selfed for at least 5 generations to produce a new inbred maize plant. One of ordinary skill could also have further crossed the new

Art Unit: 1638

inbred plant with yet another distinct inbred plant to produce a hybrid plant. One of ordinary skill in the art would have been motivated to do so, to produce new maize varieties having desired characteristics.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 3, 20, 22, and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2: the claim recites the limitation, "F1 hybrid maize seed" in line 1. There is insufficient antecedent basis for the recitation.

In claim 20: the article, "a" in the recitation, "the single locus was stably inserted into a maize genome by transformation" renders the claim indefinite. It is unclear if the genome is that of the plant of claim 11, or another plant.

In claim 22: the recitations, "yield enhancement", "improved nutritional quality" render the claim indefinite. The terms are relative and have no definite meaning. The metes and bounds of the claim are unclear.

In claim 28: the preamble of the claim indicates that the method is for developing a maize plant in a maize plant breeding program using plant breeding techniques. However, the claim does not indicate when the maize plant is developed. It is unclear when the method ends. The metes and bounds of the claim are unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn towards any maize seed produced by growing a hybrid maize plant, wherein the hybrid maize plant was produced by crossing a maize plant having all the morphological and physiological characteristics of maize plant PHJ8R with a second maize plant. As the maize seed of claim 16 is produced by growing the hybrid maize plant, and harvesting the resultant seed, the claimed seed is two generations removed from the plant having the characteristics of PHJ8R.

The specification teaches several morphological and physiological characteristics of PHJ8R in Table 1. A deposit of seed of PHJ8R has also been made with the ATCC under accession number PTA-4293, in accordance with 37 CFR 1.801-1.809. All F1 hybrid seed produced from PHJ8R inherit one set of chromosomes from PHJ8R. This structure is shared with every F1 hybrid. However, when the F1 hybrid is again outcrossed, the next generation will not inherit the haploid genome of PHJ8R. The genome of the next generation of plants will not share the same structure as the haploid genomes of the F1 generation or PHJ8R. There will therefore be wide variability in the genomic structure of the claimed maize seeds. The instant

Art Unit: 1638

specification does not describe the structure of a single second generation maize seed, or any functions (morphological and physiological traits) possessed by the claimed seed. The specification does not disclose a single maize seed that would be encompassed by claim 16. Given the breadth of the claims encompassing second generation descendants from the plant of claim 11, and the absence of a description of a single such seed, and the variability that exists among the species of the claimed genus, it is submitted that the specification fails to provide an adequate written description of the multitude of maize seeds encompassed by the claim.

8. Claims 7-10, 19-22, 25, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is drawn towards an F1 hybrid maize seed comprising an inbred maize plant cell of inbred maize line PHJ8R. There is no written description support for such a seed, or plant produced therefrom, in the specification. Claim 19 recites, "single locus conversion". Written description support is lacking for this recitation as well. While the specification discusses "single gene conversion", it does not recite single locus. Claim 25 is broadly drawn to a method of producing a maize plant derived from inbred line PHJ8R, the method comprising crossing the plant of claim 11 with any second maize plant, selfing the progeny or crossing it with a different maize plant, selfing that progeny or crossing it again with a different maize plant, and repeating these steps for an additional 0-5 generations to produce a maize plant derived from PHJ8R. In

Art Unit: 1638

the paper filed September 13, 2005, Applicant argues that support for “0-5 generations” is found in the specification on pages 3-4. However, the discussion which mentions 5 generations of crossing supports 5 generations of self crosses to produce an inbred (page 4, lines 1-9). Support is not found in the specification for the full scope of step (d) of claim 25, which encompasses the production of plants that are not inbreds. Further, there is no support for step (c) of claim 30. There is no mention of “double haploidy”, or the production of progeny without the occurrence of meiotic segregation in the specification. The claims contain NEW MATTER and must be cancelled.

9. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 is drawn towards an F1 hybrid maize seed comprising an inbred maize plant cell of inbred maize line PHJ8R. However, the specification does not enable any such seed or plant grown therefrom. By definition, a hybrid seed cannot comprise a single cell that contains a homozygous genome. Not a single F1 hybrid that has PHJ8R as a parent could have inherited two sets of chromosomes from PHJ8R, or contain a single cell that has two sets of chromosomes from PHJ8R. Neither the specification nor prior art teach how to make any such hybrid seed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 16 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson (U.S. Patent No. 5859355, issued January 12, 1999).

The claim is broadly drawn towards any maize seed, produced by growing a hybrid maize plant and harvesting the resultant seed, wherein the hybrid maize plant was produced by growing seed that was produced by crossing the plant of claim 11 with any second maize plant.

Johnson et al. teach hybrid maize seeds (claims; col. 28, line 1 to col. 31, line 14). The seed may have been produced from a method different from those of the instantly claimed seed. However, the instantly claimed products do not appear to differ from the products taught by the reference. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the

Art Unit: 1638

same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The instant claim does not recite any limitation(s) that distinguishes the product from that of the reference.

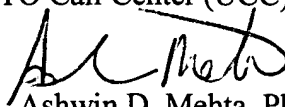
11. Claims 1-30 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner’s supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO’s Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO’s Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO’s PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

August 21, 2006


Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638

ATTACHMENT TO OFFICE ACTION

Request for Information under 37 CFR § 1.105

1. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. This request is being made for the following reasons:

Applicant is claiming a seed comprising at least one set of the chromosomes of maize line PHJ8R, PHJ8R comprising a single locus conversion, seed produced by growing a hybrid maize plant having PHJ8R as a parent. However, the instant specification is silent about what starting materials and methods were used to produce maize line PHJ8R. The requested information is required to make a meaningful and complete search of the prior art.

3. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(i) What were (are) the original parental maize lines used to produce maize line PHJ8R?

Please supply all of the designations/denominations used for the original parental maize lines and line PHJ8R. Please supply information pertaining to the lineage of the original parental lines back to any publicly available varieties.

(ii) What method and method steps were used to produce maize line PHJ8R?

(iii) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, had any of said parental maize lines or progeny therefrom been disclosed or made publicly available? If so, under what

Art Unit: 1638

designation/denomination and under what conditions were said parental maize lines or progeny disclosed or made publicly available and from when to when?

(iv) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, were any other maize lines produced by said method using said original parental maize lines, and if so, had said produced maize lines been publicly available or sold? If so, under what designation/denomination and under what conditions were said other maize lines disclosed or made publicly available and from when to when?

3. If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

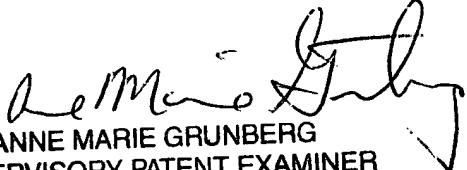
4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please indicate where the relevant information can be found.

5. The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97.

Art Unit: 1638

6. The Applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR § 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

7. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER